JUN - 4 2004

K040693

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510(k) Summary

Submitter:

BioDerm Sciences, Inc.
101 Orchard Ridge Drive, Suite 1N
Gaithersburg, Maryland 20878
Tel. (301) 216-3912
Fax (301) 216-3919

Contact Person:

Ed Gubish Ph. D. <egubish@healthpathways.com>
President, BioSciences Corp.

Preparation Date: May 27, 2004

Proprietary Device Name: BioDerm Wound Solution

Classification Name: Liquid Bandage

Predicate Devices:

Saljet Single Dose Sterile Saline Topical Solution	K993969
20 ml Normal Saline Topical Solution, 0.9% w/v Sodium Chloride	K972185
Hypertonic saline wet dressing - sterile	K941999
Dermagran wound cleanser with zinc	K945802

Description:

BioDerm Wound Solution is an acidic zinc-saline wet dressing for external wound management. **It provides an acidic, moist environment that aids the body in the healing process.** The non-irritating components of BioDerm Wound Solution allow it to be used in the mouth, eyes and on mucous membranes as well as on the skin.

BioDerm Wound Solution is supplied sterile in 50 ml injection bottles with Teflon septa and aluminum crimp caps. The dressing is applied by withdrawing the contents from the injection bottle with a syringe. The crimp caps have a pull-tab which must be removed prior to use and which make it obvious whether the bottle has been opened or not. The contents must be used within five days after opening.

Intended Use:

BioDerm Sciences Wound Solution is intended to cleanse, irrigate and externally manage dermal lesions such as lacerations, post-operative (surgical) wounds, grafts, partial and full-thickness wounds, burns and ulcers (diabetic, venous stasis, pressure). It is meant to be used in conjunction with a sterile dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).

BioDerm Wound Solution can also be used as a wound cleanser to remove foreign matter, bacteria and tissue debris.

BioDerm Wound Solution is contraindicated for use when patients are known to have had allergic reactions to this dressing or its components. It is not suitable for use on third degree burns, or for any wound for which the dermis has been severely damaged or is missing.

Comparison of Technological Characteristics:

A number of wet dressings have been cleared for marketing by the FDA. All have in common that they are saline solutions based on sodium chloride or metallic salts with a pH less than or equal to 7 (i.e. acidic). They may or may not contain additives such as nutrients. Dressings intended solely as wound cleansers are non-sterile, while those that are also intended for use as wound dressings are sterile. BioDerm Wound Solution is supplied sterile.

A broad range of chemical compositions is currently available. The chemical composition of BioDerm Wound Solution is within the range of chemical compositions of these predicate devices and is substantially equivalent in terms of its safety and effectiveness. (See Table 1)

Performance:

A study of various formulations of with varying strength levels of the metallic salts, performed at the University of Miami (Department of Dermatology & Cutaneous Surgery) using a porcine model demonstrated the effectiveness of BioDerm Wound Solution as an aid to healing of incision, grafts, burns, partial and full-thickness wounds. (Appendices B-E)

Conclusions:

When used as directed, BioDerm Wound Solution is safe and effective as a wound cleanser or wet dressing.

Other Information:

This product is intended for sale by or on the order of a physician (or properly licensed practitioner).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

Edward R. Gubish, Ph.D.
President
BioDerm Sciences, Inc.
101 Orchard Ridge Drive, Suite 1N
Gaithersburg, Maryland 20878

Re: K040683
Trade/Device Name: BioDerm Sciences Wound Solution
Regulatory Class: Unclassified
Product Code: MUG
Dated: March 9, 2004
Received: March 16, 2004

Dear Dr. Gubish:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

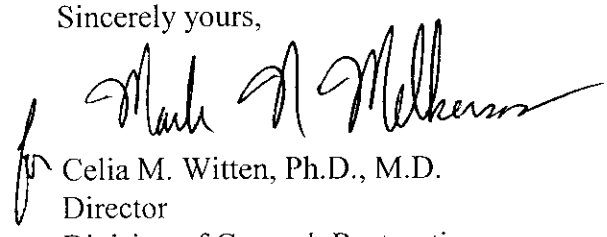
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040683

Indications for Use

510(k) Number: K040683

Device Name: BioDerm Sciences Wound Solution

Indications for Use:

BioDerm Sciences Wound Solution is intended to cleanse, irrigate and externally manage dermal lesions such as lacerations, post-operative (surgical) wounds, grafts, partial and full-thickness wounds, burns and ulcers (diabetic, venous stasis, pressure). It is meant to be used in conjunction with a sterile dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).

Prescription Use__X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040683